

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

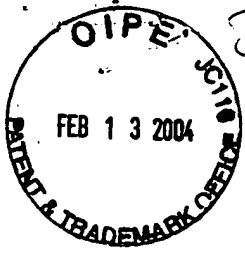
Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



2-18-04

1634

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: SJ-0029  
Inventors: Schuetz et al.  
Serial No.: 09/974,619  
Filing Date: October 10, 2001  
Examiner: Johannsen, Diana B.  
Group Art Unit: 1634  
Title: Genotyping Assay to Predict CYP3A5 Phenotype

"Express Mail" Label No. EV215113675US  
Date of Deposit - February 13, 2004

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, Mail Stop Sequence, P.O. Box 1450, Alexandria, VA 22313-1450.

By Kathleen A. Tyrrell  
Typed Name: Kathleen A. Tyrrell, Reg. No. 38,350

Commissioner for Patents  
Mail Stop Sequence  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

RESPONSE TO NOTICE TO COMPLY

In response to the "Notice to Comply" dated January 13, 2004, a response to which is due February 13, 2004, enclosed herewith is:

- (XX) Amendment under 1.825;
- (XX) Statement to Support Filing and Submission in Accordance with 37 CFR §§1.821 through 1.825;
- (XX) Paper copy of the Sequence Listing;



(XX) Copy of the computer readable form of Sequence Listing;

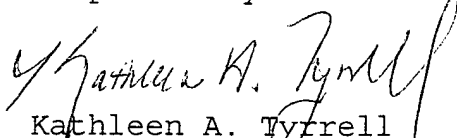
(XX) Copy of Notice to Comply;

( ) Petition for One (1) Month Extension of Time;

( ) Other:\_\_\_\_\_.

The Commissioner is hereby authorized to charge any underpayment associated with this communication or credit any overpayment to Deposit Account No. 50-1619. This sheet is attached in duplicate.

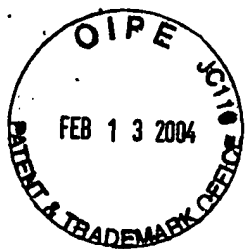
Respectfully submitted,

  
Kathleen A. Tyrrell  
Registration No. 38,350

Date: February 13, 2004

Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: SJ-0029  
Inventors: Schuetz et al.  
Serial No.: 09/974,619  
Filing Date: October 10, 2001  
Examiner: Johannsen, Diana B.  
Group Art Unit: 1634  
Title: Genotyping Assay to Predict CYP3A5  
Phenotype

"Express Mail" Label No. EV215113675US  
Date of Deposit - February 13, 2004

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, Mail Stop Sequence, P.O. Box 1450, Alexandria, VA 22313-1450.

By Kathleen A. Tyrrell  
Typed Name: Kathleen A. Tyrrell, Reg. No. 38,350

Commissioner for Patents  
Mail Stop Sequence  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**AMENDMENT**

In response to the "Notice to Comply" dated January 13, 2004, a response to which is due February 13, 2004, please replace the current Sequence Listing with the amended Sequence Listing provided herewith. Amendments to this Sequence Listing were made to correct a typographical error in the number of nucleotides listed for SEQ ID NO:49 and to remove inadvertent characters at the end of the sequence. No new matter has been added by this amendment.



Applicants are also providing herewith a Statement that the provided CRF copy of the Sequence Listing is identical to the amended paper copy of the Sequence Listing submitted herewith.

Entry of this amended Sequence Listing is respectfully requested.

Respectfully submitted,

Kathleen A. Tyrrell

Registration No. 38,350

Date: February 13, 2004

LICATA & TYRRELL P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

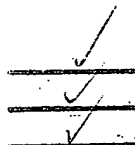
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,619	10/10/2001	Erin Schuetz	44158/244344	8446

7590

01/13/2004

Jane Massey Licata  
Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, NJ 08053

Docket System  
Status Report  
Docket Book



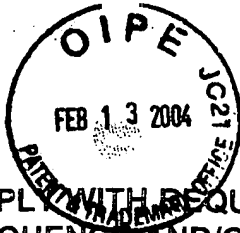
EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
----------	--------------

1634  
DATE MAILED: 01/13/2004  
Notice to Comply With Rule  
of Practice dated 1/13/04  
2/13/04  
(MAX) 7/13/04

Please find below and/or attached an Office communication concerning this application or proceeding.



Application No.: **09/974,619**

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. \_\_\_\_\_

**Applicant Must Provide:**

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

Technical Assistance.....703-287-0200

To Purchase PatentIn Software.....703-306-2600

**PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY**

Art Unit: 1634

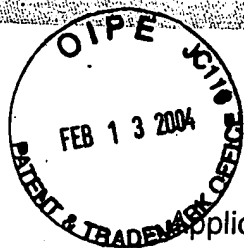
1. The reply filed on October 7, 2003 to the Notice to Comply of September 9, 2003 was not fully responsive for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Since the above-mentioned reply appears to be a *bona fide* attempt to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), applicant is given a TIME PERIOD of **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this communication, whichever is longer within which to correct the deficiency so as to comply with the sequence rules (37 CFR 1.821 - 1.825) in order to avoid abandonment of the application under 37 CFR 1.821(g). EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761 through January 13, 2004, and 571/272-0744 beginning January 14, 2004. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152 through January 13, 2004, and 571/272-0745 beginning January 14, 2004. The fax phone number for the organization where this application or proceeding is assigned is 703/872-9306.





Application/Control Number: 09/974,619  
Art Unit: 1634

Page 3

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-1234.

A handwritten signature in cursive script that reads "Diana B. Johannsen".

Diana B. Johannsen  
Patent Examiner  
January 8, 2004